K103698
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510(k) Summary

JUN 2 1 2011

Date of Summary prepared: April 27th, 2011

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Submitted Device:

Generic name: Pelvic Floor Stimulator
Trade name: TensCare itouch Sure
Common name: itouch Sure Pelvic Floor Exerciser
Classification name: Stimulator, Electrical, Non-implantable, for Incontinence – Title 21, Code of Federal Regulations Sec.876.5320 ProCode: 78 KPI
Device Classification: Class **II**
Predicate Devices: Innova Pelvic Floor Stimulation System by EMPI. K941911
Kegel 8 Pelvic Muscle Trainer by NE Services. K81480

The class of the predicate Devices: Class II

Device Description:
The itouch Sure is a small lightweight battery powered single channel neuromuscular stimulation device supplied with a vaginal two electrode stimulation probe.
The probe connects to the control unit by cable and plug.

The unit is intended for home use by the patient, and is designed with simplicity and ease of use in mind. It has four preset treatment programs, an adjustable treatment timer, a compliance monitor, and open circuit detectors.

The intended use of the device:
The itouch Sure is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women

The intended use and indications for use of the new device are the same as those of the predicate devices.

Technological Comparison:

	Itouch Sure	EMPI Innova K941911	Kegel 8 K81480
Intended Use	Treatment of urinary incontinence	Treatment of urinary incontinence	Treatment of urinary incontinence
Programmable features	Intensity,program session length	Intensity, 12.5/50 Hz, Duty cycle: 5-5/5-10 session length	Intensity, session length, Hz, us, Work, Rest, Ramp
Preset Programs	4	Duty cycle: 5-5/5-10	9 +manual
Power source	2x1.5V AA	9V PP3	9V PP3
Mode of operation	Intermittent	Intermittent	Intermittent
Frequency Hz	10/20/35/50	12.5/50	2-100
Pulse Width uS	200/250/300	300	50-450
Duty cycle	5/10 and 3/6	5-5/5-10	Selectable
Output current	0-45V = 0-90mA over 500 Ohm	0-60mA (100mA override)	0-90 mA nominal
Intensity steps	200	Rotary	100
Timing control		Continuous/15/30 min	
Output type	Constant current 160-500 Ω, Constant voltage 500-1500 Ω	Nominally constant current up to 1kΩ	Nominally constant current
No of electrodes	1	1 (optional anal probe)	2
Usage conditions	Intermittent	Intermittent	Intermittent
Controls	6 Push buttons + lock button on side	Two rotary intensity Duty cycle slider switch Intensity override switch	6 Push buttons + 2 concealed buttons
Probe length mm	88		87
Probe diameter mm	28		26
Electrode orientation	Axial		Axial
Electrode material	Stainless Steel		Stainless Steel
Electrode placement	Vaginal		Vaginal
Waveform Type	Bi-phasic	Bi-phasic	Bi-phasic
Waveform Shape	Rectangular at positive	Irregular Rectangular	Rectangular at positive

Output waveforms: The Sure output waveform is substantially equivalent to that of the Kegel 8. The difference in shape of negative phase is not clinically significant.

Biocompatibility

The materials of the vaginal electrode are exactly the same as the materials of the Kegel 8 probe by NE Systems.

Body material: Acrylonitrile-Butadiene-Styrene copolymer (ABS)
Conductor Material: Stainless steel

Biocompatibility tests to ISO 10993-5:2009 and -10:2002 on the vaginal electrode have shown no cytotoxicity, negligible vaginal irritation, and no sensitisation.

Labelling Comparison: The Labelling is substantially equivalent to that of the predicate devices.

Safety information: Designed to comply with relevant safety applicable recognized consensus standards; the output energy is controlled well within the safety and effectiveness ranges specified by relevant FDA guidance. Detailed and strictly controlled testing has been carried out.
Test results, Risk Analysis, and FMEA analysis show that the new unit itouch Sure is safe with no hazard.

itouch Sure has been marketed in Europe since April 2009. During this period a review of Customer Complaints, Returned Product and the results of Post Market Feedback, has demonstrated that the product has performed as intended, to its' Specified Requirements.
The new device itouch Sure controls the output at constant voltage above 500 Ω load. Below this it controls the output at a pseudo constant current, with output voltage reducing to zero as load reduces. This characteristic reliably makes the device safe.

EMC testing: The Sure has been tested to EN60601-1-2:2007 and found to be suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Submitted times: This is the first submission to FDA for this new device

Conclusion: The itouch Sure unit is substantially equivalent to the predicate devices and any differences between the devices do not pose any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Andrew Brown
Regulatory Affairs Manager
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UNITED KINGDOM KT19 9BE

JUN 2 1 2011

Re: K103698
Trade/Device Name: Tenscare itouch Sure Pelvic Floor Exerciser
Regulation Number21 CFR §876.5320
Regulation Name: Non-implanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: May 18, 2011
Received: May 18, 2011

Dear Mr. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103698

Section 4
Indications for Use

510(k) Number (if known):

Device Name : Tenscare itouch Sure Pelvic Floor Exerciser

Indications for Use

The itouch Sure is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103698

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)